

National Center for Environmental Assessment (NCEA)

Tina Bahadori, Director

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Briefing Prepared for Richard Yamada

June 16, 2017

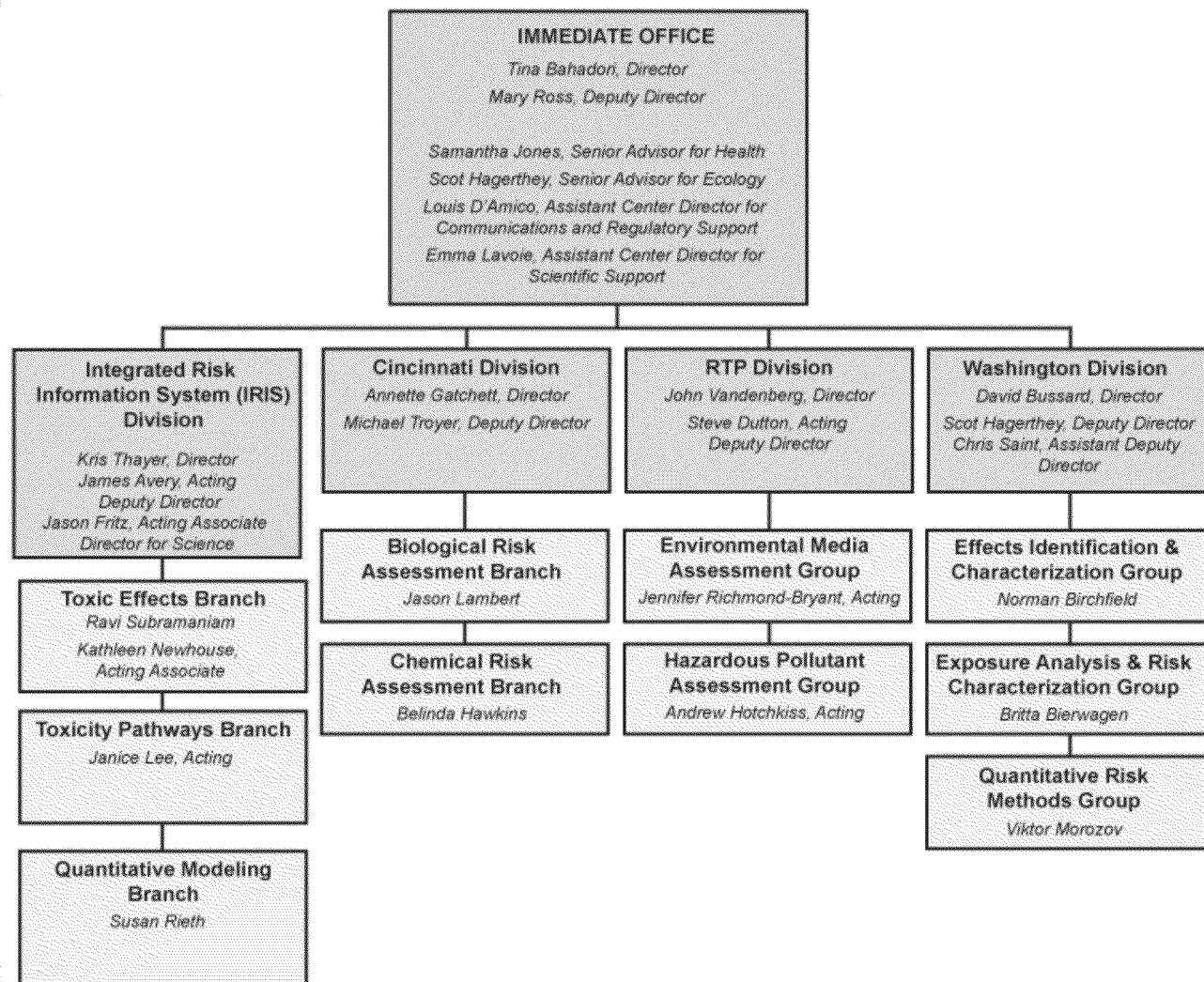


Outline

- **Overview of NCEA**
- **Overview of IRIS and IRIS in 2017**
- **Inside IRIS Processes**
- **Visible Products in Calendar Year 2017 (CY 17) Pipeline**
- **Open Discussion**



NCEA Organization



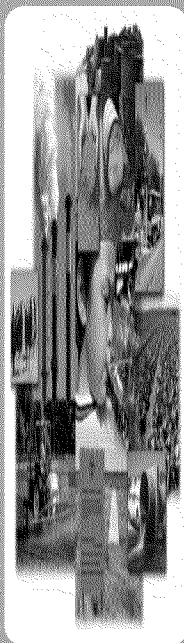


NCEA At-A-Glance

NCEA

\$37.1 M; 181.1 FTE

HHRA



- IRIS
 - \$2.6M; 56.6 FTE
- ISAs
 - \$0.8M; 26.0 FTE
- PPRTVs & Superfund Support
 - \$1.2M; 13.2 FTE
- Advanced Analyses
 - \$1.2M; 5.6 FTE

ACE



- Multi-environmental stresses on:
 - Health & Air;
 - Water & Ecosystems; and
 - Urban Systems
- \$1.1M; 8.8 FTE

SHC



- Report on the Environment (ROE)
- \$0.4M; 5.1 FTE

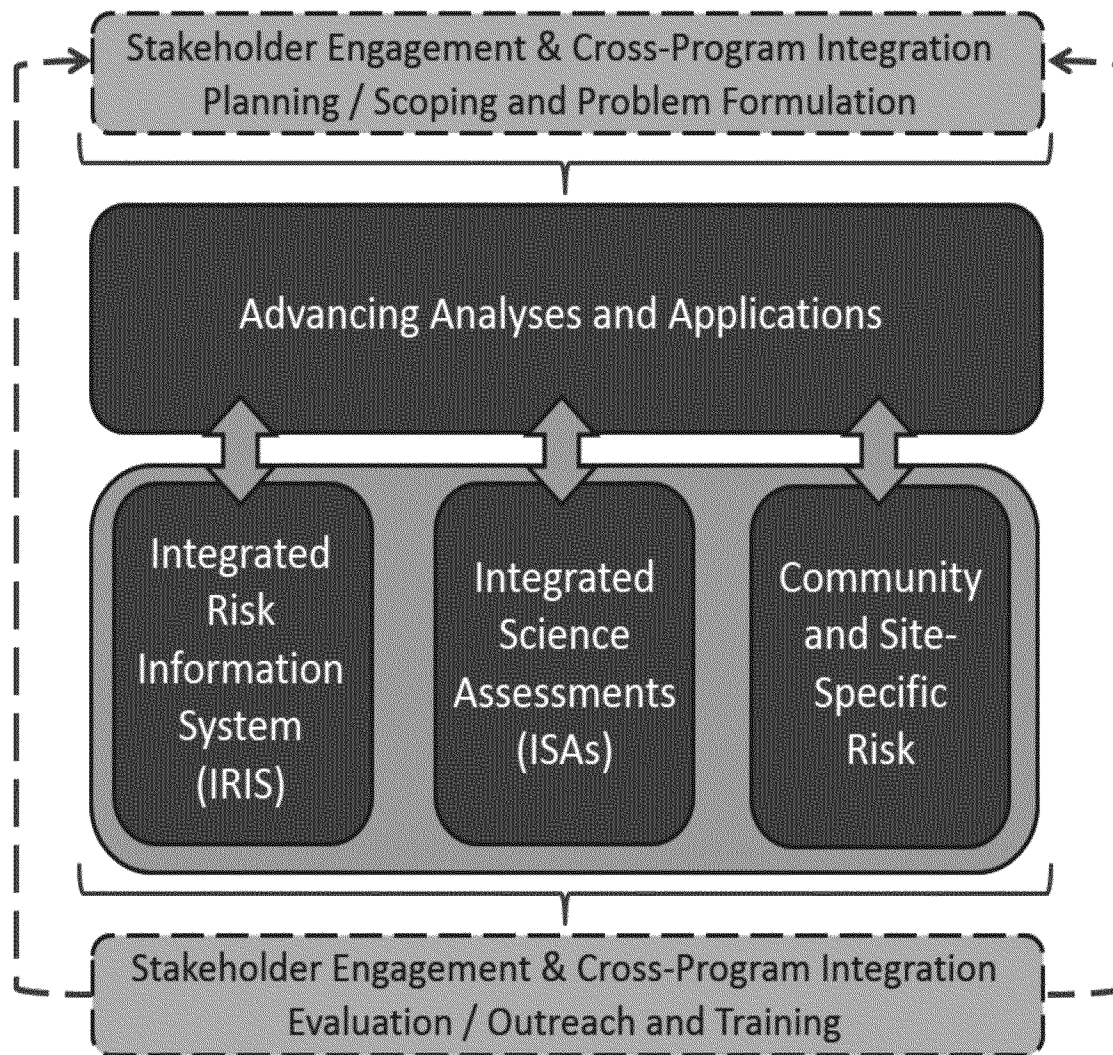
SSWR



- Hydraulic Fracturing Assessment
- Ecological Causal Assessment
- \$0.3M; 8.8 FTE



NCEA Human Health Risk Assessment



Briefing:
July 17

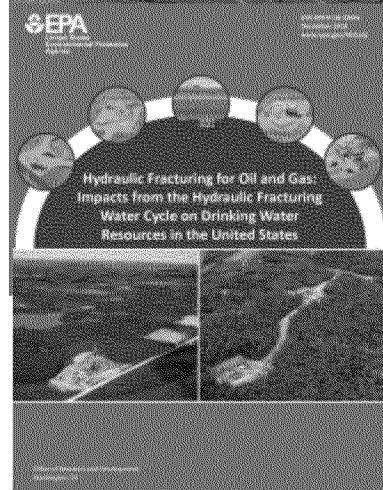
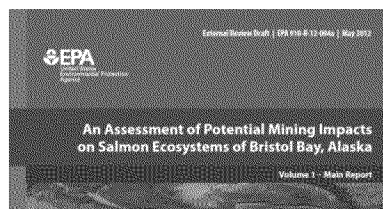
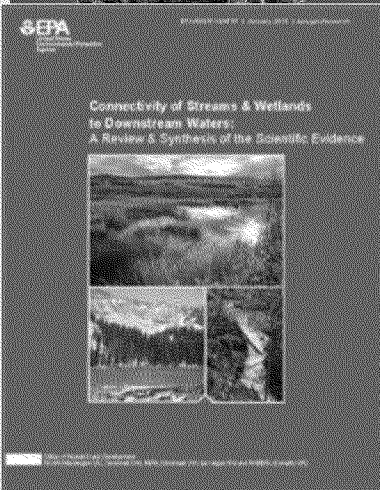
Briefing:
June 27



NCEA Environmental Assessments

Working with partners in EPA programs, states, regions, local communities, and the international community, we provide mission-critical, high-quality, defensible environmental assessments and tools that provide the scientific foundations required for informed decision making.

- 2014- Bristol Bay Assessment **7/27**
- 2015- Connectivity of streams and wetlands to downstream waters **7/27**
- 2015- EPA's Report on the Environment (www.epa.gov/roe) **6/27**
- 2016- Hydraulic Fracturing for oil and gas **7/26**
- 2016- Regional climate change monitoring networks
- 2017- PM/SOx/NOx Integrated Science Assessments



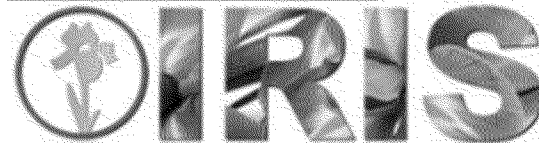


New Leadership Structure

- **In January 2017, EPA appointed new leadership to the National Center for Environmental Assessment and to its IRIS Program.**
 - **With significant experience in the chemical industry, and formerly the Director of ORD's Chemical Safety for Sustainability National Research Program, the new NCEA Director brings knowledge of TSCA, innovative applications of computational toxicology, and exposure science.**
 - **As a recognized leader in systematic review, automation, and chemical evaluations, the new IRIS Program Director brings experience in early partner and stakeholder engagement and input, and demonstrated actions to increase capacity and transparency in assessments.**
- **Improved responsiveness and accountability through Senior Leadership Team**
 - **NCEA IO**
 - **Divisions**
 - **Integrating across the spectrum of human and ecological RA practices**

IRIS

Kris Thayer, Division Director



- **Created in 1985 to foster consistency in the evaluation of chemical toxicity across the Agency.**
- **IRIS assessments contribute to decisions across EPA and other health agencies**
 - **Health-based national standards**
 - **Health-based clean-up levels at local sites**
 - **Health-based advisory levels**
 - **Information for the general public**
 - **Ranking across chemicals**
 - **Cost-benefit analyses**
- **Toxicity values**
 - **Noncancer: Reference Doses (RfDs) and Reference Concentrations (RfCs).**
 - **Cancer: Oral Slope Factors (OSFs) and Inhalation Unit Risks (IURs).**
- **IRIS is the only federal program to provide toxicity values for both cancer and non-cancer effects.**

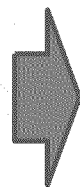


IRIS Addresses Agency Priorities and Mandates

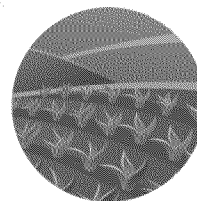
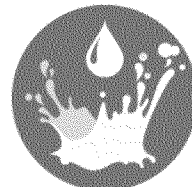
↑
IRIS
↓

- Clean Air Act (CAA)
- Safe Drinking Water Act (SDWA)
- Food Quality Protection Act (FQPA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- Resource Conservation and Recovery Act (RCRA)
- Toxic Substances Control Act (TSCA)

Broad
Input to
Support

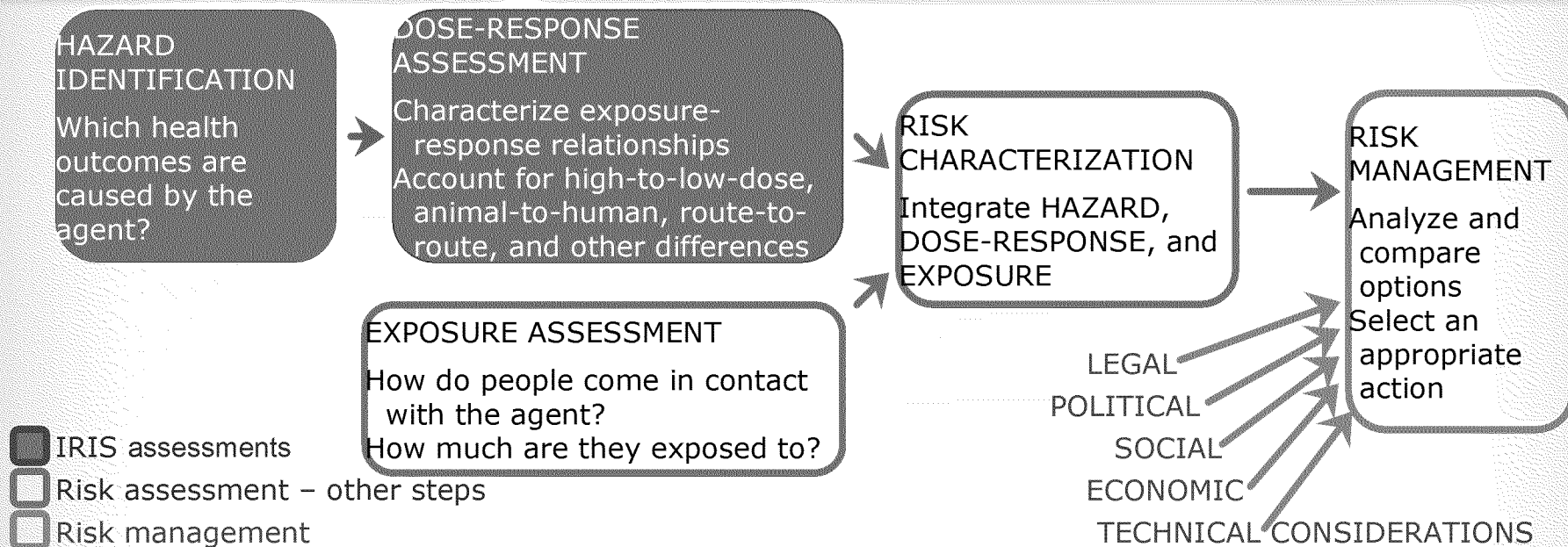


- Agency Strategic Goals
- Children's Health, Environmental Justice





IRIS, Risk Assessment, and Risk Management



- IRIS address two parts of the risk assessment process (Hazard Identification and Dose-Response Assessment). Risk Assessment is separate from the policy considerations of Risk Management.
- IRIS assessments have no direct regulatory impact until they are combined with
 - extent of exposure to people, cost of cleanup, available technology, etc.
 - regulatory options, which are the purview of EPA's program offices.



GAO and NRC Reports

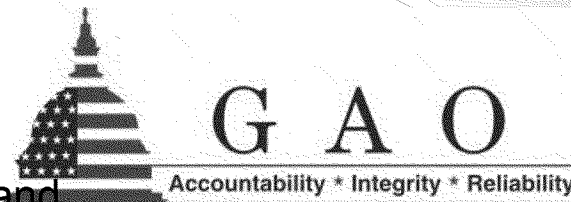
GAO Reports Observations

2008: low productivity, OMB-led interagency review

2011: Continued low productivity, unaddressed issues with clarity and transparency of assessments, outdated information on status of ongoing assessments.

2013: No recent evaluation of needs for IRIS assessments, need for criteria for selecting chemicals for assessment.

GAO High Risk List: 2015, 2017

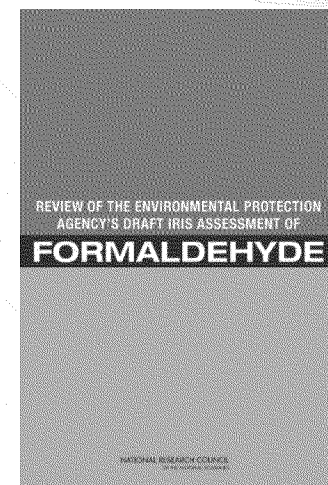


NRC 2011 Report Observations

“ . . . recurring methodologic problems”

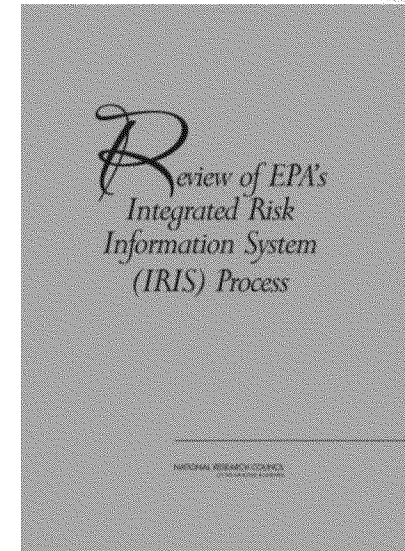
“ . . . problems with clarity and transparency of the methods appear to be a repeating theme over the years . . .”

“ . . . the draft was not prepared in a consistent fashion; it lacks clear links to an underlying conceptual framework; and it does not contain sufficient documentation on methods and criteria . . .”



NRC Commends Agency Revisions to the IRIS Process

“Overall, the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report. The NRC formaldehyde committee recognized that its suggested changes would take several years and an extensive effort by EPA staff to implement. Substantial progress, however, has been made in a short time, and the present committee’s recommendations should be seen as building on the progress that EPA has already made.” [p 9]



“...the IRIS program has moved forward steadily in planning for and implementing changes in each element of the assessment process. The committee is confident that there is an institutional commitment to completing the revisions of the process . . .” [p 135]



GAO 2017 Report

- **Acknowledged the actions ORD has taken to enable the IRIS Program to produce timely, transparent, and credible assessments in support of EPA's mission.**
- **Discussions with GAO during and after the release of the 2017 High Risk Report have focused on approaches to demonstrate how management and integrity initiatives within IRIS are supporting the transformation of the program, and warrant removal from the High Risk List**

Summary of 2015 and 2017 GAO High Risk Criteria Ratings of the IRIS Program

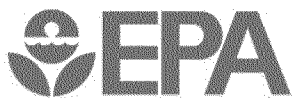
GAO High Risk Criteria	2015 Rating	2017 Rating
Leadership Commitment	Met	Met
Monitoring	Partially Met	Met
Action Plan	Partially Met	Partially Met
Demonstrated Progress	Not Met	Partially Met
Capacity	Not Met	Partially Met

- **IRIS recommendations from the 2006, 2012, and 2015 reports.**
- **Of the seventeen recommendations issued in these three reports, as of June 2017, we have successfully closed ten recommendations and are rapidly moving to address the remaining seven.**



How is IRIS Focusing

- **Supporting EPA Mission**
- **Refocus the IRIS Program -- to better support policy and regulatory decisions for EPA's programs and regions, as well as state agencies, annually confirm list of priority chemicals and product needs, and align with appropriate distribution and prioritization of resources.**
- **Eyes on TSCA – in addition to Superfund, water, air, and children's health drivers, prioritize the expedited needs of modernized TSCA and support for Office of Pollution Prevention and Toxics.**



Innovating Risk Assessment Workflow & Systematic Review

- **Modernize the IRIS Program**

- through the use of innovative applications in computational toxicology, automation, and machine learning, implement and expedite systematic review methods.

- **Modularize product lines**

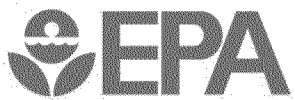
- implement a portfolio of chemical evaluation products that optimize the application of the best available science and technology for a diversity of clients beyond EPA, including states, tribal nations, and other federal agencies.

- **Increase transparency**

- develop assessment plans that define user needs, frame the scientific questions, and outline the evidence that will be collected prior to draft development; seeking public input at this stage promotes transparency and ensures interested stakeholders are fully aware of IRIS Program activity.

- **Enhance accessibility**

- provide outreach and training to make systematic review practices ubiquitous and more accessible; enhance data sharing through publicly available software platforms for assessments developed by EPA, other federal and state agencies, industry, academia and other third-parties.



In Addition to TSCA, What Does IRIS Do?

Provides a critical part of the scientific foundation for decision-making by EPA's Program and Regional offices under an array of environmental laws (e.g., Clean Air Act, Safe Drinking Water Act, and Comprehensive Environmental Response, Compensation, and Liability Act). For example,

- **EPA Office of Land and Emergency Management (OLEM) does not conduct its own risk assessments. OLEM relies on IRIS to inform EPA's clean-up decisions at contaminated Superfund and hazardous waste sites.**
- **Support statutory requirements to conduct Risk and Technology Reviews under Title III of the Clean Air Act. There is a court ordered deadline to review 20 source categories in 3 years.**
- **TSCA addresses chemicals in commerce. It does NOT support other activities such as site cleanups, drinking water evaluations, etc. IRIS provides these types of support across EPA, and for states and tribal nations.**
- **IRIS also evaluates naturally occurring chemicals (like manganese) and chemical degradants.**

Next Generation IRIS

- IRIS in the 21st Century – implement recommendations of the NAS 2017 report, Using 21st Century Science to Improve Risk-Related Evaluations; collaborate with EPA's National Center for Computational Toxicology (NCCT) to build expert-judgement case studies that inform assessment development and fill gaps in assessments, especially for data poor chemicals; inform where resources should be strategically invested to generate additional data.

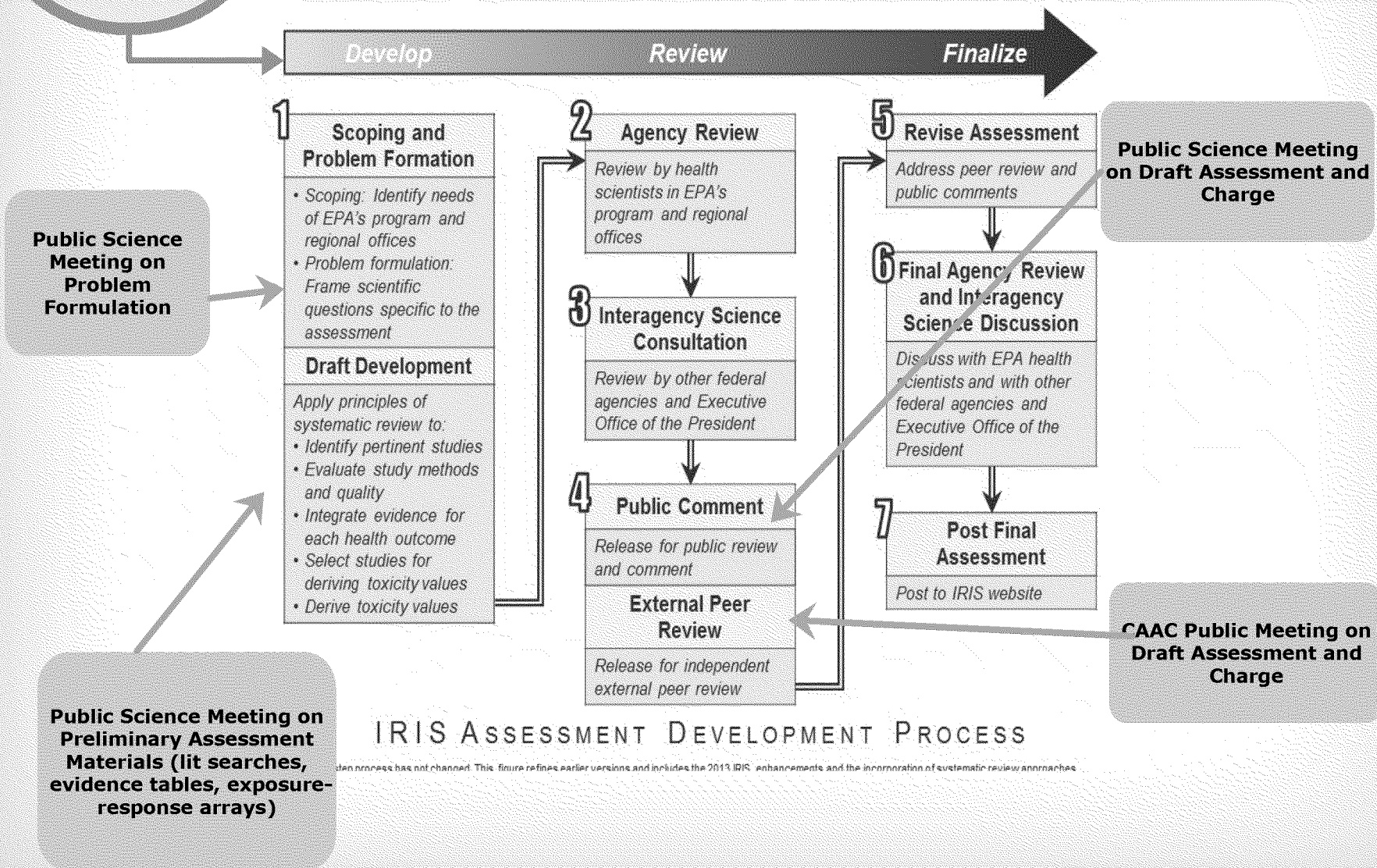
Improved Management Practices

- Create efficiencies – engage other agencies to share common practices, data, and tools, and more efficiently leverage resources across the federal government.
- Improve timeliness and responsiveness – deploy program and project management tools to more effectively and efficiently utilize human resources to ensure timely delivery of products.

Inside IRIS Processes

Priority Setting

2013 Enhanced Process: Multiple Opportunities for Public Engagement

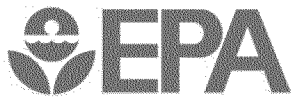




IRIS Multi-Year Agenda

Developing Agenda
Survey EPA program and regional offices for their assessment needs
Estimate the resources needed for each assessment by science discipline
Discuss with senior EPA officials how to meet the most high-priority needs
Allocation of IRIS resources based on the plan
Released to the public
December 2015
Evaluate annually for continued relevance

Group	Chemicals
1	Manganese
	Mercury/methylmercury
	Nitrate/nitrite
	Perfluoroalkyl compounds
	Vanadium and compounds
2	Acetaldehyde
	Ammonia (oral)
	Cadmium and compounds
	Uranium
3	Di-(2-ethylhexyl) phthalate
	Dichlorobenzene isomers
	Methyl t-butyl ether (MTBE)
	Nickel and compounds
	Styrene



Priority Setting

- 1. Publicly solicit nominations**
 - EPA programs/regions, states, and stakeholders**
- 2. Evaluate feasibility of conducting assessments**
- 3. Work with programs/regions to prioritize based on statutory requirements and urgent needs**
 - Regions reflect state and tribal priorities**
- 4. Further prioritize using published criteria**
- 5. Final list published in Federal Register and website (IRIS Agenda)**
 - Signals a data call to stakeholders**



IRIS Criteria for Chemical Selection

- **Potential public health impact**
- **EPA statutory, regulatory, or program-specific implementation needs**
- **Availability of new scientific information or methodology that might significantly change the current IRIS information**
- **Interest to other governmental agencies or the public**
- **Availability of other scientific assessment documents that could serve as a basis for development of an IRIS assessment**
- **Other factors such as widespread exposure**

Statutory Relevance – an example

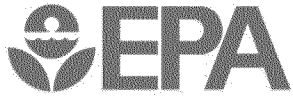
Chemical	EPA SRS Listing of Applicable Statutes and Regulations	Program/ Regional Office Priority
HBCD	New TSCA 1 st 10 chemicals TSCA 5(a) SNUR TSCA 12(b) Export TSCA 5(a) Final TSCA 8A PAIR TSCA 8D HSDR (a) TSCA 8D TERM	OCSPP/OPPT OLEM Region 2, 5
Formaldehyde	CAA 109, 111,112R CAA 202A CAA112(b) HAP CAA112(b) HON CERCLA CWA 311 EPCRA 302 EPCRA 313 FIFRA-Inerts RCRA Appendix VII RCRA Appendix VIII RCRA U Waste SARA 110 SDWA NPDWR	OAR/OAQPS OW OA/OCHP OCSPP/OPP
RDX	SARA 110 TSCA Inv UCMR 1999	OLEM Region 10

Redacted



Other Interactions with Programs/Regions

- **Monthly Agency-wide IRIS meetings for updates, priority check-ins, science discussions, and assessment status**
- **Programmatic (HHRA) Quarterly Highlights Meetings**
- **Risk Assessment Forum (RAF), Science and Technology Policy Council (STPC), and various cross-agency workgroups (e.g., PFAs)**
- **OLEM Human Health Regional Risk Assessor's Forum**
- **IRIS Agency review process for assessments**
- **IRIS public science meeting discussions of key issues in IRIS assessments, including scoping/problem formulation, systematic review materials, and draft assessments**



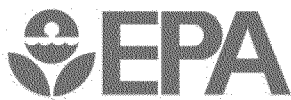
Additional Interactions with States

- **ECOS/ERIS/ITRC**
- **IRIS Hotline and the Risk Assessment webpage inquiries**
- **Technical support related to hazard and dose-response assessment**
- **State participation in peer reviews of IRIS products**
- **IRIS public science meetings**
- **Collaborations on science and risk assessments issues**
- **Communications, controlled correspondence, and other inquiries**

Hot Items for Calendar Year 2017 (CY17)

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-
-
- **Appropriations Language: Transmit to NAS for peer review (Step 4b)**
 - NAS reconvening majority of original peer review committees for each chemical, with potentially some overlap.
 - Peer review might take 1+ years
- **Overarching charge to the Committee**
 - Peer review for science
 - Peer review for responsiveness to NAS recommendations to changes to IRIS



Other Visible Products in the Pipeline

- **Other assessments with public milestones in 2017**
 - **ETBE and TBA: ETBE and TBA will undergo peer review by the SAB Chemical Assessment Advisory Committee (CAAC) in Summer 2017**
 - **Public conference call: July 11**
 - **Face to face meeting: August 15-18**
 - **RDX: IRIS anticipates receiving a final report from the SAB-CAAC on their review of the draft IRIS assessment for RDX in Fall 2017**

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- **Strengthened peer review and conflict of interest policies**
 - **Constituted the EPA Science Advisory Board Chemical Assessment Advisory Committee.**
 - **Contract-managed peer review will be conducted by a committee in a highly public process.**
- **Engaged stakeholders in the planning, scoping, and problem formulation phase.**
- **Adoption of best practices in systematic review**
- **Adoption of “data integration” or “weight-of-evidence” approaches in selection and analysis of published studies.**
- **Developed stopping rules to facilitate consideration of late-breaking studies without delaying an assessment.**
- **Public comment on draft IRIS assessments prior to peer review.**

Open Discussion

More on TSCA support
Other opportunities for improvement



More on Supporting TSCA

- **New impetus from mandates and timelines of modernized TSCA**
- **IRIS engagement with TSCA staff has escalated in the last several months with 15-20 staff currently working in direct support of the first 10 chemical assessments, providing:**
 - **chemical specific expertise for scoping and evaluating health hazard information;**
 - **quality checks for work completed by contractors;**
 - **training and assistance in implementing best practices of systematic review and evidence synthesis.**
- **IRIS staff are also helping to develop automated software workflows directed at expediting the pace and throughput of TSCA assessments.**
- **Support will increase as evaluations are started beyond scoping stages, and as OPPT works to meet the statutory requirements for having 20 chemical assessments in development at a time.**
- **Aiming to shorten NCEA chemical evaluation timeline to ~2 years (pre- peer review) and more consistent with TSCA timelines.**
- **Working to develop portfolio of assessment products relevant to TSCA**